UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,703	03/17/2006	Markus Storr	04623.0010	5360

22852 7590 01/29/2010

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
MELLON, DAVID C	

ART UNIT	PAPER NUMBER
1797	

MAIL DATE	DELIVERY MODE
01/29/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/572,703	STORR ET AL.	
	Examiner	Art Unit	
	DAVID C. MELLON	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/8/2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/8/2010 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-26, 35, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horl et al. (USP 5,556,708) and in view of Pitt et al. (USP 5,037,656).

Regarding claims 1, 3-11, 13-14,16-24, 26, 35, and 39, Horl et al. discloses a process for grafting of polymers and polymers obtained thereby (Title) comprising:

- Providing a solid substrate having a substrate surface wherein amino functional groups are coupled to the substrate surface and formed as a membrane or fibers (C5/L10-20 – substrate, specifically "polyamides", C5/L40-45 – primary amino groups which are biocompatible, C7/L1-19 - fibers, membranes);
- Covalently coupling the amino functional groups with a reducing agent (C8/L1-15, C11/L28-33 – the reducing agent would couple covalently with the amino functional groups due to chemical attraction when exposed in an aqueous or liquid environment with the reducing agent and utilizing a thermal activation, C11/L43-50);
- Contacting the substrate surface with a solution of polymerizable monomers wherein graft copolymerization of the monomers forms a

structure of adjacent functional polymer chains on the substrate surface (C6/L15-60, specifically see also C8/L2-44).

- Horl further discloses using water alone as the reaction medium (C4/L50-60 - "the process of the invention is advantageously carried out in water as reaction medium" *emphasis added*. Further with regards to the reaction medium, Applicant has not explicitly required that an organic solvent not be used but rather that the graft copolymerization does not require it. This implies that an organic solvent may be used in the process.

Horl et al. does not disclose the use of a thermally labile radical initiator to promote the polymer grafting process.

Pitt et al. discloses a composite porous membrane formed from a porous polymer membrane (Abstract) comprising:

- Providing a porous membrane (C3/L1-5)
- Covalently coupling a thermally labile radical initiator to the membrane (C4/L30-40 – see exemplary compounds, specifically "4,4'-azobis-(4-cyanovaleric acid)" - also see C3/L58-66)
- Contacting the substrate surface with a polymerizable monomer solution (C4/L12-28 – see exemplary monomers, see also C3/L58-67).

Horl et al. and Pitt et al. are combinable because they are concerned with the same field of endeavor, namely that of graft polymerization membrane structures.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the membrane and process of Horl et al. to use an azo compound

such as 4,4'-azobis-(4-cyanovaleric acid) as a thermally labile radical initiator to promote graft polymerization as taught by Pitt et al. for the purpose of providing a more effective, rapider polymerization process to eliminate the need for additional crosslinking agents when using a functionalized substrate (see also Pitt C3/L1-11).

Specifically regarding claim 1, Applicant is noted that the claim is a product-by-process type claim. Accordingly, Applicant must either further define the product or provide evidence of its difference from that of the prior art. Regarding the method limitations recited in claim(s) 1, the examiner notes that even though a product-by-process is defined by the process steps by which the product is made, determination of patentability is based on the product itself. In re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). As the court stated in Thorpe, 777 F.2d at 697, 227 USPQ at 966 (The patentability of a product does not depend on its method of production. In re Pilkington, 411 F.2d 1345, 1348, 162 USPQ 145, 147 (CCPA 1969). If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.).

Regarding claims 2 and 15, modified Horl et al. discloses all of the claim limitations as set forth above. Horl et al. further discloses that the nylon 6,6 support membranes are discloses as having a pore diameter of 0.2 micrometers which would be sufficient to allow the passage of blood serum (C20/L15-25, C21/L45-50).

Regarding claims 12 and 25, modified Horl et al. discloses all of the claim limitations as set forth above. Horl et al. does not explicitly set forth the use of dimethylaminopropyl acrylamide. However, Horl et al. does in fact set forth the use of

monomers of acrylic and methacrylic acid (C6/L26-30) and further sets forth the use of dimethylaminopropyl methacrylamide (C6/L41-42). Accordingly, dimethylaminopropyl methacrylamide and dimethylaminopropyl acrylamide have art recognized equivalent function and properties such that they have become recognized as similar equivalents (see Galleguillos et al., USP 6361768 as evidentiary in column 6 where both are recognized as functional cationic monomers). It would have been obvious to one of ordinary skill in the art at the time of the invention to use dimethylamionpropyl acrylamide instead of dimethylaminopropyl methacrylamide as the art recognizes the equivalence of the two compounds and the selection of any known equivalent would have been within the level of ordinary skill in the art.

6. Claims 27-30, 32, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horl et al. (USP 5,556,708), in view of Pitt et al. (USP 5,037,656), and further in view of Bell et al. (USP 6,774,102).

Regarding claims 27-29 modified Horl et al. discloses all of the claim limitations as set forth above. Horl et al. does not explicitly set forth the use of the separating material as for endotoxin removal from blood or affinity adsorption applications.

Bell et al. discloses a blood treating material to remove endotoxins by adsorption (abstract) using a polydisperse amino hollow fiber or activated polymer beads (C6/L35-60) and specifically affinity adsorption (C3/L25-45).

Horl et al. and Bell et al. are combinable because they are concerned with the same field of endeavor, namely that of amino functional polymers.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify use the separation material produced by Horl et al. as a hollow fiber or bead for removal of endotoxins via affinity adsorption as taught by Bell et al. for the purpose of improved blood endotoxin removal.

Regarding claim 30, modified Horl et al. discloses all of the claim limitations as set forth above. Horl et al. does not explicitly set forth the use of the separating material as beads in a separating column.

Bell et al. discloses a blood treating material to remove endotoxins by adsorption (abstract) using a polydisperse amino hollowfiber or activated polymer beads (C6/L35-60) and specifically affinity adsorption (C3/L25-45). Bell et al. further discloses packing the beads into polycarbonate columns for blood purification (C7/L15-40).

Horl et al. and Bell et al. are combinable because they are concerned with the same field of endeavor, namely that of amino functional polymers.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify use the separation material produced by Horl et al. as a bead for removal of endotoxins via affinity adsorption in a separation column as taught by Bell et al. for the purpose of improved blood endotoxin removal.

Regarding claims 32 and 36, modified Horl et al. discloses all of the claim limitations as set forth above. Horl et al. further discloses the membrane is fibrous (C7/L1-15).

Bell et al. discloses a blood treating material to remove endotoxins by adsorption (abstract) using a polydisperse amino hollowfiber polymer(C6/L35-60) and specifically affinity adsorption (C3/L25-45).

Horl et al. and Bell et al. are combinable because they are concerned with the same field of endeavor, namely that of amino functional polymers.

It would have been obvious to one having ordinary skill in the art at the time of the invention to utilize the fiber based separation material of Horl et al. and form hollow fiber membranes as taught by Bell et al. for the purpose of blood filtration.

7. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Horl et al. (USP 5,556,708), in view of Pitt et al. (USP 5,037,656), in view of Bell et al. (USP 6,774,102), and further in view of Duggins (USP 4,668,399).

Regarding claim 31, modified Horl et al. discloses all of the claim limitations as set forth above. Horl et al. does not explicitly disclose a separating cartridge with a tube, and potting hollow fibers in it.

Duggins discloses a hollow fiber plasmapheresis module in figures 1-3 comprising a hollow fiber membrane module (14) which is shown in figure 3 as a tube with hollow fibers in it. Furthermore, it is well known that in hollow fiber membrane modules, the fibers are potted to secure them.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the hollow fiber membrane of modified Horl et al. in a hollow fiber membrane module as taught by Duggins for the purpose of plasmapheresis.

8. Claims 33-34, and 37-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horl et al. (USP 5,556,708), in view of Pitt et al. (USP 5,037,656), and further in view of Steuck (4,618,533).

Regarding claims 33-34 and 37-38, modified Horl et al. discloses all of the claim limitations as set forth above. Horl et al. does not explicitly set forth the use of copolymers that are hydrophilizing.

Steuck discloses a composite porous membrane formed from a porous polymeric membrane (abstract) which is exposed to a monomer and an initiator (C3/L45-66) wherein hydrophilizing copolymers are utilized as the substrate (C2/L60-C3/L11).

Horl et al. and Bell et al. are combinable because they are concerned with the same field of endeavor, namely that of thermally labile polymer radical grafting.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the polymer membrane of Horl et al. such that the substrate is formed from a hydrophilic copolymer as taught by Bell et al. for the purpose of improving the separation capacity and increasing the water affinity.

Response to Amendment

9. The Declaration under 37 CFR 1.132 filed 1/8/2010 is insufficient to overcome the rejection of claims 1 and 14 based upon Horl in view of Pitt as set forth in the last Office action because:

The Declaration of Markus Storr has been reviewed and considered in its entirety. The Declaration is insufficient to overcome the rejection of the claims for several reasons as stated below:

The declaration is not commensurate with the scope of the claims. For instance, the claims as currently stated do not require reduction of the primary or secondary amines.

The declaration concludes that secondary or primary amino groups cannot be further reduced. Accordingly, since Applicant uses graft copolymerization and free radical polymerization (the process using thermally labile radical initiators requires formation of a radical and results in free radical polymerization, see for instance Pitt reference), the reasoning of the Applicant cannot establish that the primary and secondary amino groups of Horl cannot be graft copolymerized. Further with regards to the method of Horl, Applicant has not provided evidence made of the record which establishes that the method of Horl does not in fact work. The mere allegation that the mechanism of Horl is unclear is not sufficient to establish that the instant claims are non-obvious. Furthermore with regards to the Horl reference, Horl does not require that the primary or secondary amino groups are physically reduced besides being grafted.

Applicant's instant claims and specification utilize the same initiator as taught in from the Pitt reference. Accordingly, if the primary and secondary amino groups of Horl cannot be used for such a method, then it is further not possible for the Applicant's method to perform an identical process with the same materials.

Response to Arguments

10. Applicant's arguments filed 1/8/2010 have been fully considered but they are not persuasive.

Applicant's arguments are primarily a re-discussion of the declaration of inventor Storr. See discussion of the declaration above. With regards to Applicant's arguments that the primary or secondary amines cannot be reduced to become activated to react, this argument is not convincing because Horl does not require explicitly that the primary or secondary amines be reduced. Furthermore, Applicant's argument that Horl provided no examples is not persuasive. The reference discloses that such a process works, accordingly, Applicant must provide evidence to differentiate the instant claims and prove that the prior art method does not in fact work. With regards to the CCl4 of Horl, this is not a required component. See rejection above and Horl at C4/L50-60 where CCl4 can be used to improve the solubility range.

With regards to the argument that Pitt provides no reason that it can be used with primary or secondary amines, this argument is not persuasive. Furthermore, with regards to the instant claims, the claims do not specify that the amines are actually being reduced or coupled directly. Accordingly, pendant amines as functional groups still read on the claims. Furthermore, the compound of Pitt is in fact a reducing agent and further provides for free radical polymerization which is the same general method performed by Horl.

With regards to Pitt using water as solvent, Horl further uses water as a solvent, see C4/L50-60. Additionally, applicant's argument of negative results is unsubstantiated and without evidence.

Furthermore, with regards to the argument that the mechanism of Horl is not fully known, this argument is not persuasive because it does not further provide any distinguishing features of the instant claims from the prior art.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID C. MELLON whose telephone number is (571)270-7074. The examiner can normally be reached on Monday through Thursday 9:00am-5:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tony G Soohoo/
Primary Examiner, Art Unit 1797

/D. C. M./
Examiner, Art Unit 1797